IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Serial No.:	10/821,499		
Filed:	April 09, 2004	Customer No.:	27581
Examiner:	Dilek B. Cobanoglu	Group Art Unit:	3626
Docket No.:	P0011232.00/1111-067US01		
Title:	DATA EXCHANGE WEB SERVICES FOR MEDICAL DEVICE SYSTEMS		

CERTIFICATE UNDER 37 CFR 1.8 I hereby certify that this correspondence is being transmitted via the United States Patent and Trademark Office electronic filing system on June 14, 2010.

By: _____

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
Alexandria, VA 22313-1450

Sir:

Applicant respectfully requests a Pre-Appeal Brief Review, based on the Examiner's failure to establish a *prima facie* case of obviousness under 35 U.S.C. § 103. As outlined below, the applied references would not have rendered the combination of elements recited in Applicant's independent claims obvious. In addition, it would not have been obvious to one of ordinary skill in the art to combine the cited references. For these reasons, the claims should be allowed. Applicant does not assert that the clear grounds of error presented below are the only errors in the Office Actions, and does not waive additional arguments that may be asserted in an Appeal Brief.

In the Final Office Action of February 1, 2010 claims 1 and 4-20 were rejected as unpatentable over Nelson et al. (U.S. Patent No. 6,480,745, hereinafter "Nelson") in view of Stawikowski et al. (U.S. Patent Publication No. 2002/0046239, hereinafter "Stawikowski"), and in further view of Trusheim et al. (U.S. Patent No. 6,385,589, hereinafter "Trusheim"). The applied references collectively fail to disclose or suggest the inventions defined by Applicant's claims, and there is no apparent reason for further modification to arrive at the claimed invention. In addition, there is no apparent reason to combine Nelson, Stawikowski, and Trusheim.

Independent claims 1, 19, and 20 recite systems for exchanging medical data. As an example, the system of claim 1 includes a means for acquiring medical data, a means for handling medical data wherein medical data may be stored, analyzed, or displayed, and one or more devices configured to provide a plurality of web services for performing a data exchange function between the means for acquiring medical data and the means for handling medical data. One of the web services is a translation web service having an input method configured to receive medical data in a first format,

and an output method configured to return the medical data in a plurality of output formats. The translation web service is further configured to receive a request for one of the plurality of output formats from an invoking application, and the output method is configured to return the medical data to the invoking application in the requested output format.

The Examiner has not set forth a *prima facie* case of obviousness for each and every element of claim 1. As one example, none of the references cited by the Examiner, alone or in combination, teaches or suggests "a translation web service having an input method configured to receive medical data in a first format, and an output method configured to return the medical data <u>in a plurality of output formats</u>." The Examiner correctly noted that Nelson does not teach the translation service required by Applicant's claim 1, but cited Trusheim to overcome this limitation of Nelson. While Applicant does not acquiesce as to the Examiner's interpretation of any of the applied references, Applicant respectfully submits that Trusheim fails to overcome the limitations of Nelson with respect to the requirements of Applicant's claim 1.

Trusheim describes a medical data system that can be used for practicing preventative medicine.[1] The system of Trusheim includes a translator 31 that receives source data files 30, which are stored in a variety of legacy systems in a variety of legacy formats.[2] The translator 31 is used to translate the source data files 30 into a common format.[3] For example, the translator 31 includes a translation program that receives a data file having a first format and translates the data file into an output file having a second, standard format.[4] The translation program utilizes data maps to translate data files from the variety of first formats to the second format.[5]

As described by Trusheim, the primary function of the translator is to provide mapping of source data files (comprised of a variety of legacy data having different formats) to standard data elements and code value names.[6] As shown in Fig. 3 of Trusheim, the translator 31 is connected only to source data files 30 and a bus adapter program 35a.

Trusheim does not teach or suggest "a translation web service having an input method configured to receive medical data in a first format, and an output method configured to return the medical data <u>in a plurality of output formats</u>." In fact, the Examiner appears to concede that Trusheim does not teach receiving medical data in a first format, and returning medical data in a plurality of output formats. In the Office Action dated July 6, 2009, the Examiner asserted that "Trusheim teaches translating the data from one format to another, therefore it teaches a structure necessary to configure the data in a plurality of formats."

The Examiner's argument improperly conflates the ability of hardware to convert data into a single format, and the ability of hardware to convert and output data in multiple formats. Trusheim relies on a series of unidirectional maps to convert data stored in a variety of legacy formats into a single, common format. Trusheim makes clear that the output format is a <u>standard</u> format. For

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[1] Trusheim, col. 1, lines 6-15.
[2] *Id.* at col. 8, lines 5-9.
[3] *Id.*
[4] *Id.* at col. 8, lines 9-15.
[5] *Id.*
[6] *Id.* at col. 8, lines 15-30.

example, as described above Trusheim states that the "primary function of translator 31 is to provide mapping of source data files to <u>standard</u> data elements and code value names."

Contrary to the assertion of the Examiner, the translator 31 of Trusheim could not be used to convert source data in a variety of different formats, e.g., due to the Trusheim translator only having unidirectional maps with a single output format. The Examiner relies on personal opinion in the assumption that the translator 31 of Trusheim can be used to return the medical data <u>in a plurality of output formats</u>. Trusheim does not teach or suggest returning data in a plurality of output formats, and the Trusheim translator is incapable of doing so.

As another example, none of the references cited by the Examiner, alone or in combination, teaches or suggests a "translation web service...configured to receive a request for one of the plurality of output formats from an invoking application, and the output method is configured to return the medical data to the invoking application in the requested output format."

As described above, the Examiner appears to concede that Trusheim does not teach receiving a request for one of a plurality of formats, and returning medical data in the requested output format, as recited in claim 1 of the present application. Rather, the Examiner's argument is that the hardware of Trusheim could be used in place of the claimed system. Despite the ability of Trusheim to convert one data format into another, it does not necessarily follow that the hardware of Trusheim is capable of receiving a request for one of a plurality of formats, and returning data in the requested output format. For example, the ability to receive a request for one of a plurality of formats may require additional processing capabilities for receiving the request, interpreting the request, and returning the requested format.

Again, the Examiner relies on personal opinion, rather than any teaching in the cited references, when assuming that the translator 31 can be used to receive a request for one of a plurality of formats, and return data in the requested output format. As shown in Fig. 3 of Trusheim, the translator 31 is connected only to source data files 30 and a bus adapter program 35a. There is no apparatus present for receiving a desired format input. It is an oversimplification to assert that the hardware for data conversion to a single format can necessarily be used for receiving a request for one of a plurality of formats, and returning data in the requested output format.

Trusheim fails to teach or suggest receiving "translation web service...configured to receive a request for one of the plurality of output formats from an invoking application," and returning the medical data "in the requested output format," as required by claim 1. Trusheim is limited to outputting data in a single format, without the ability to receive a request for an output format that is one of a plurality of output formats. Likewise, Nelson and Stawikowski also fail to disclose these requirements of Applicant's claim 1. Consequently, Nelson in view of Stawikowski and Trusheim fails to teach, suggest, or disclose the translation web service required by claim 1.

The Examiner has also failed to set forth a *prima facie* case of obviousness for the claims, because it would not have been obvious to one of ordinary skill in the art to have combined the disclosures of Nelson, Stawikowski, and Trusheim to arrive at the claimed invention.

According to the Supreme Court, the Examiner must "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does."[7] It is impermissible hindsight for the Examiner to use the motivation stated in Applicant's own disclosure as a blueprint to reconstruct the claimed invention from the prior art.[8] Rather, the Examiner's rejection must be based on substantial evidence in the record demonstrated that the motivation for making the claimed invention resides in the prior art.

As described above, claim 1 recites a web service as a service for performing a data exchange function between the means for acquiring medical data and the means for handling medical data. In contrast, the translator 31 of Trusheim is intended to convert files stored in various legacy data systems into a single, common format. Furthermore, Trusheim is not related to a translation *web service* that performs a data exchange function between two means, as recited in claim 1.

The Examiner incorrectly asserted that the web server 50 of Trusheim being in communication with the translator 31 somehow supports the assertion that Trusheim includes a translation web service. Contrary to the Examiner's assertion, the translation services provided by the translator 31 of Trusheim are performed wholly within the translator 31.[9] As described above, the translator 31 simply converts input data into a common output format. The fact that the translator 31 may have some attenuated connection to a web server does not transform the translator 31 into a translation web service.

Trusheim is also not at all related to a translation web service that performs a data exchange function between two means as required by Applicant's claim 1, and the translator 31 of Trusheim is not a web service. Moreover, none of the applied references include any teaching for modifying translator 31 of Trusheim to make it a web service. For example, Trusheim includes no teaching as to how to modify its teachings to comply with receiving any other sort of input data, e.g. medical data from a means for acquiring medical data or a means for handling medical data as required by Applicant's claim 1. Neither Nelson nor Stawikowski reveal how one could modify the teachings of Trusheim to arrive at the web service of Applicant's claim 1.

Accordingly, even if one of ordinary skill in the art had found a reason to combine the applied references, one would not have arrived at the requirements of Applicant's claim 1 from their combination.

Claims 19 and 20 include elements similar to those recited in claim 1. Claim 19, for example, recites a translation web service having an input method configured to receive medical data in a first format and an output method configured to return the medical data in a plurality of output formats. The translation web service is configured to receive a request for one of the plurality of output formats from an invoking application, and the output method is configured to return the medical data to the invoking application in the requested output format. Claim 20, for example, recites a translation web service having an input method configured to receive medical data in a first format

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[7] *KSR v. Teleflex*, 127 S.Ct. 1727 (2007).

[8] *See Interconnect Planning Corp. v. Feil*, 227 USPQ 543 (CAFC 1985); *see also In re Fine*, 5 USPQ2d 1596, 1598 (CAFC 1988); *see also In re Gorman*, 18 USPQ 2d 1885, 1888 (CAFC 1991); *see also Al-Site Corp. v. VSI International, Inc.*, 50 USPQ2d 1161, 1171 (CAFC 1999).

[9] *See Trusheim*, Fig. 3.

and an output method configured to return the medical data in a plurality of output formats. The translation web service is further configured to receive a request for one of the plurality of output formats from an invoking application, and the output method is configured to return the medical data to the invoking application in the requested output format. Accordingly, claims 19 and 20 are patentable for at least the same reasons claim 1 is patentable.

With specific reference to dependent claim 15, the Examiner continues to inappropriately rely on Official Notice, despite Applicant's continued request for a reference demonstrating that it is well known in the information network arts to register a patient and/or medical device in a web service, and provide an objective reason for further modification of the cited reference in view of the cited references. In fact, in the Final Office Action dated February 2, 2010, the Examiner attempted to shift the burden to the Applicant to separately argue the patentability of the claim without the Examiner first providing an anticipatory reference.
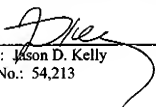
Official notice without documentary evidence to support an Examiner's conclusion is permissible only in some circumstances.[10] While "official notice" may be relied on, these circumstances should be rare when an application is under final rejection or action under 37 CFR 1.113.[11] It is not appropriate for the Examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known.[12] For example, assertions of technical facts in the areas of esoteric technology or specific knowledge of the prior art must always be supported by citation to some reference work recognized as standard in the pertinent art.[13]

The Examiner has failed to cite a reference demonstrating that it was, at the time the application was filed, well known in the information network arts to register a patient and/or medical device in a web service, and provide an objective reason for further modification of the cited references in view of the cited reference.

For at least these reasons, the Examiner has failed to establish a *prima facie* case for non-patentability of Applicant's claims under 35 U.S.C. § 103(a). Accordingly, the rejections issued in the Final Office Action of February 2, 2010 should be reversed.

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[10] *See* MPEP 2144.03.
[11] *Id.*
[12] *See In re Ahlert*, 165 USPQ 418, 420-421 (CCPA 1970).
[13] *Id.*